

Eric J. Conn (202) 909-2737 (direct) econn@connmaciel.com

April 22, 2022

Mr. Douglas Parker Assistant Secretary of Labor for OSHA Occupational Safety and Health Administration U.S. Department of Labor - OSHA 200 Constitution Avenue, N.W. Washington, DC 20210

Re: Comments on Occupational Exposure to COVID-19 in Healthcare Settings Permanent Standard; Occupational Safety and Health Administration; Docket No. OSHA-2020-0004

Dear Assistant Secretary Parker,

I am pleased to submit the following comments, on behalf of a coalition of employers in the retail industry who operate pharmacies or provide other health services (vision services, etc.) within their retail locations, on the Occupational Safety and Health Administration's ("OSHA") proposed permanent COVID-19 standard applicable to the healthcare industry.

The employers in the coalition include a diverse group of national retail employers with millions of employees across thousands of workplaces in every state in the Nation. They fill billions of prescriptions yearly and help millions of customers obtain and use medicines correctly and safely, while offering innovative services that improve health and health care affordability.

### Introduction

The retail pharmacy industry has been on the forefront of the fight against the coronavirus since its inception with no adverse effect on pharmacy staff. Pharmacies have administered more than 234 million COVID-19 vaccinations to date; in fact, today, two of every three COVID-19 vaccine doses are provided at a pharmacy. Critically important to the protection of the underserved community, more than 40 percent of those vaccinated at pharmacies were from racial and ethnic minority groups; half of pharmacy COVID-19 vaccination sites are located in areas with high social vulnerability. Additionally, pharmacies have provided more than 11,000 mobile COVID-19 vaccination clinics across the country, and provide more than 20,000 COVID-

19 testing sites nationwide, with 70 percent of such sites are in areas with moderate to severe social vulnerability.<sup>1</sup>

In terms of protecting their own employees, our coalition members implemented thoughtful and effective COVID-19 prevention plans even before the first state's COVID-19 emergency rule went into effect in 2020 and have achieved tremendous success in mitigating the spread of the coronavirus in their workplaces. And, since the rollout of safe and efficacious vaccines last year, the industry has been deeply involved in the campaign to achieve a vaccinated U.S. workforce. Indeed, the vast majority of pharmacists (upwards of 90%) and a good majority of pharmacy staff across the board are fully vaccinated, in large part due to the efforts of this industry to support, facilitate, encourage and in some instances require their pharmacists and pharmacy staff to become vaccinated.

The coalition appreciates and values the role OSHA has played in fighting the pandemic. We submit these comments to help OSHA develop and scope a permanent COVID-19 standard that is protective of healthcare workers at *significant risk* of being exposed to COVID-19, without hindering the vital efforts of the retail pharmacy to continue the national fight against COVID-19.

We do not believe OSHA's COVID-19 standard should apply to retail pharmacies.<sup>2</sup> While the industry provides vital healthcare every day to millions of customers, including in the area of COVID-19, its workforce is not exposed to the coronavirus in any way equivalent to those healthcare workers employed at hospitals (and/or nursing care facilities) for whom this standard was designed. OSHA's COVID-19 standard is designed to protect workers who are in close contact all shift/all day or night with hospital patients who are severely ill with COVID-19. This exposure is simply not present at retail pharmacies, even for pharmacies that offer COVID-19 testing, and certainly not for pharmacies that offer vaccinations and immunizations, whether they be for COVID-19, shingles, pneumococcal, or Tdap.

Accordingly, we request OSHA exempt retail pharmacy activities from coverage of the standard by expanding the exemption for dispensing drugs at 29 C.F.R. Section 1910.502(a)(2)(ii). If OSHA does not expand the retail pharmacy exemption, we urge the agency to preserve the non-hospital ambulatory care exemption at 29 C.F.R. Section 1910.502(a)(2)(iii) so pharmacy employers can avail themselves of this exemption by continuing the COVID-19 screening of pharmacy clients.<sup>3</sup> Finally, we provide recommendations to OSHA regarding the contents of the

<sup>&</sup>lt;sup>1</sup> While we do not have comprehensive data, information from one coalition member that provides general immunizations, COVID vaccination, and COVID testing shows that its pharmacy staff accounted for only 9.2% of the COVID cases its employees reported.

<sup>&</sup>lt;sup>2</sup> These comments assume that OSHA is not considering expanding coverage of the permanent COVID-19 standard to the non-pharmacy/non-medical portions of retail stores. If OSHA were to expand the standard in such a fundamental way, the law would require stakeholders to have an opportunity to comment on that expansion. Such an expansion would be wholly unnecessary, infeasible, and legally unsupportable.

<sup>&</sup>lt;sup>3</sup> These comments are further supported by the overall vaccination rate in the country combined with the emerging variants of the coronavirus, which have resulted in significantly less severe illness and hospitalizations.

standard it is developing to help ensure that the final standard is effective in its purpose – to minimize workplace transmission of COVID-19 – and reasonable in its burdens.

We provide support for these recommendations below.

### Section One: Scope of the Standard

### I. The COVID-19 Standard Should Exempt Pharmacy Operations in Retail Settings.

In addition to dispensing prescriptions, which OSHA has already recognized as an activity conducted by pharmacists that does not pose sufficient risk to trigger coverage under the standard, pharmacists regularly conduct a number of other activities, including the administration of immunizations (of all sorts, such as pneumococcal, influenza, shingles, Tdap, etc.); COVID-19 vaccinations; and some provide COVID-19 testing. None of these activities pose a level of risk of exposure to COVID-19 that approaches the risk posed to healthcare workers in hospitals.<sup>4</sup> While the industry follows the Centers for Disease Control ("CDC") recommendations related to personal protective equipment ("PPE"), such as masking, when performing some of these commonplace activities, such as COVID-19 testing, application of the entire OSHA COVID-19 standard with its plethora of requirements appropriate for hospitals is not necessary for these activities.

#### Non-COVID-19 Immunizations and COVID-19 Vaccinations and Boosters

Long before the COVID-19 pandemic, retail pharmacies were intimately involved in immunizing the Nation with the development of immunization centers in pharmacies, which provided an easy, cost-effective way for providing vital protections to a large segment of the US population. Rather than making and getting to a doctor's appointment, basic immunization protections for a host of diseases could be obtained at an individual's local pharmacy.

Provision of immunizations provides no increased risk of COVID-19 transmission than the exchange that occurs between pharmacist and patient when dispensing prescriptions or the patient and front counter clerk once the patient leaves the immunization area and stands in the check-out line after having shopped for homecare products. This is because: (1) the patient is unlikely to be infectious with COVID-19 in the first instance; (2) it takes only approximately 5 minutes for the entire immunization process (including answering any questions, preparing the bandage, the administration of the shot, and excusing the patient from the room); and (3) pharmacies follow CDC guidelines for personal protective equipment for infection control.

<sup>&</sup>lt;sup>4</sup> The coalition recognizes and agrees with OSHA that certain medical services that may be embedded within the retail environment (e.g., walk-in clinics located within segregated, walled areas of a retail store that are staffed by medical professionals and are separate and distinct from pharmacy operations) potentially present different exposure risks than the ordinary pharmacy setting in which clinical-type operations such as immunizations are limited and performed quickly. The coalition believes that these medical clinics should also be able to avail themselves of the screening exemption discussed herein at Section II and that the applicability of a COVID-related standard to those segregated clinic environments should not affect an exemption applicable to the retail pharmacy environment as a whole.

There is nothing inherently risky about providing vaccinations. In fact, the CDC makes clear that people with suspected or confirmed COVID-19 should not get vaccinated until they complete their applicable isolation/quarantine period. *See* CDC "Frequently Asked Questions about COVID-19 Vaccination" (updated April 15, 2022) (snipped below).

Can I get vaccinated against COVID-19 while I am currently sick with COVID-19?

No. People with COVID-19 should wait to be vaccinated until after they <u>complete their isolation period</u>. People who have symptoms will end isolation at a different time than people who do not have symptoms. This also applies to people who have been vaccinated but get COVID-19 before getting any additional or booster doses.

People who have had a known COVID-19 exposure should not seek vaccination until their <u>quarantine period</u> has ended to avoid potentially exposing healthcare personnel and others during the vaccination visit. This recommendation to wait also applies to people with a known COVID-19 exposure who have received their first dose and are in need of <u>additional or booster doses</u>.

The coalition believes that the general population adheres to this CDC recommendation. Accordingly, those who come into the pharmacy for their COVID-19 vaccination are likely self-selected as "not confirmed or suspected to have COVID-19." Additionally, there is no reason to believe that someone coming into the pharmacy for, a shingles vaccine would be a confirmed or suspected COVID-19 case either, and certainly would be unlikely to be sick with COVID-19. The industry is unaware of any information to suggest that the universe of people who are seeking to be immunized at retail pharmacies – either for COVID-19 or other disease – present any significant risk of being infectious. Certainly, they present no more elevated risk of being infectious than the customers who enter retail pharmacies for purposes other than healthcare.

Application of the COVID-19 standard to pharmacies for providing vaccinations and immunizations would impose serious burdens on employers in the industry – with no commensurate benefit. Exempting vaccinations and immunizations from coverage under the standard would significantly unburden the industry from onerous compliance obligations that challenge the industry and inhibit and hinder the Administration's objective of making vaccinations widely available.

<u>COVID-19 Testing</u>. The retail pharmacy industry has worked hand-in-hand with the Biden Administration to develop COVID-19 vaccination and testing programs that have helped millions and saved thousands of lives during the pandemic. As with vaccinations, OSHA should take no action that disincentivizes or hampers industry employers from continuing these efforts, which are essential components of the Nation's Path out of the Pandemic.

During the effective period of the ETS, a large majority of pharmacy employers relied on the screening exemption to screen out COVID-19 positive or suspect cases from entering the pharmacy area of retail locations. By doing so, they were able to avoid application of the standard.

Some pharmacies have the capacity and capability to conduct testing outdoors, using drive-up windows or tented areas in parking lots to conduct testing, but these options are limited with a significant segment of the industry unable to build outdoor testing venues. Thus, without an exemption, pharmacies will be faced with the choice of either complying with the burdensome terms of the standard or not offering testing programs. Some portion of the industry may choose the latter option. Establishing policy that even minimally disincentives robust COVID-19 testing options would be completely contrary to the express policy of this Administration.

We appreciate that, unlike the population who present themselves for vaccination/immunization, the universe of clientele presenting themselves for COVID-19 testing may hold a higher percentage of COVID-19 cases. Notwithstanding, the risk presented to pharmacy staff administering the testing, even if done indoors, does not approach the risk presented to healthcare workers providing patient care in hospital settings to severely ill COVID-19 patients. The time it takes, from start to finish, to administer a COVID-19 test, is less than 1 minute, closer to 30 seconds. During this time, the tester is protected by the personal protective equipment recommended by CDC, including at minimum gloves and a surgical mask, in addition to face shield and goggles. There is not a comparison between this interaction and that of a nurse tending to a severely ill COVID-19 patient in a hospital bed.

The COVID-19 standard OSHA is developing is designed to protect against the high-risk present in hospital settings. A centerpiece of the standard includes compliance with the standard and transmission-based precautions in accordance with CDC's "Guidelines for Isolation Precautions." This provision alone would be nearly impossible for retail pharmacies to meet. Its entire context assumes a non-ambulatory care setting where patients are stationary and bed-ridden.

# II. The Permanent Standard Presents Technological, Feasibility, and Operational Challenges for the Industry Feasibility Concerns for Retail Pharmacies.

Compliance with the permanent COVID-19 standard would present serious technological feasibility concerns and operational challenges for the industry. While we have not developed a comprehensive set of concerns, there are a few that stand out. For instance, compliance with the physical distancing requirement poses significant challenges. The proposed standard states, "[t]he employer must ensure that each employee is separated from all other people by at least 6 feet when indoors unless the employer can demonstrate that such physical distancing is not feasible for a specific activity (e.g., hands-on medical care)." *See* 29 C.F.R. Section 1910.502(h)(1).

In many pharmacy settings, because of the layout and preconfigured space it is literally impossible to maintain physical distances among pharmacy staff. Staff need to be within six feet of each other to fill prescriptions, a central role of the pharmacy staff.

Additionally, in many retail stores, the pharmacy is located within 6 feet of grocery aisles and other shopping areas. To comply with the distancing provision in these situations, stores would be required to literally reconfigure their grocery/retail areas in order to maintain a six-foot

distance between pharmacy staff and retail shoppers. This simply is not feasible and would be incredibly expensive.

Although the physical distancing provision expressly incorporates an element of feasibility into the requirement, OSHA provided guidance that "[t]he burden is on the employer to demonstrate that it is infeasible to comply with the required physical distancing for a specific activity or workspace. If the employer can demonstrate that the space cannot be expanded, and that multiple employees must be in that space at the same time (i.e., that there are no other feasible alternatives that would permit 6 feet of physical distancing), the employer satisfies its burden under the physical distancing requirements. However, in such cases, employers must ensure that employees maintain as much physical distance as possible." *See* OSHA Healthcare ETS FAQs #28. Employers are concerned about having to demonstrate infeasibility, particularly because compliance officers might issue citations without a thorough review of infeasibility, leading employers to then have to expend, if they can, significant resources towards defending citations when a combination of the pharmacy space configurations combined with operational necessity prevent social distancing during substantial segments of employees' shifts.

On top of the feasibility issue, this creates a nonsensical situation. The standard would create the obvious complexity for customers/patients in retail facilities that have pharmacies and vision services embedded within their retail locations where those embedded services are not separate from the general retail area. Thus, in many situations, customers waiting in line at the pharmacy and the pharmacy associates would be required to wear masks whereas customers and store employees only a few feet away would not. Hence, while shopping for aspirin, no mask would be required to mask, but when waiting in line at the pharmacy five feet away the customer would be required to wear a mask. This is totally unworkable.

Another significant concern of the coalition is that N95s are required when an employee is in close contact with a suspect or positive COVID-19 case. The use of mandated N95s triggers the requirements under 29 C.F.R. Section 1910.134 to conduct medical evaluations and fit testing. It would be nearly impossible to coordinate fit testing across tens of thousands of pharmacies, not to mention the financial burden this would place on the employers.<sup>5</sup>

# III. At Minimum, the COVID-19 Standard Should Preserve the Non-Ambulatory Care Screening Exemption included in the ETS.

Without an expansion of the retail pharmacy exemption to cover the types of activities that are vital to millions of customers, pharmacies will need to continue to rely on the screening exemption to avoid coverage of the standard. There is ample support for preserving this exemption in the permanent standard.

<sup>&</sup>lt;sup>5</sup> At minimum, fit testing and medical evaluations should not be required in this context. Remember, only a few months ago the Administration offered to mail out up to 500 million N95s for use by the general public. No fittesting or medical evaluations was required to use these N95s, even when they were to be used by children as young as 8 and adults as old as 80. Under the totality of circumstances, if N95s are going to be required for this industry, fit testing and medical evaluations should not be required.

The coalition understands that OSHA is considering elimination of the exemption because it believes the less rigorous threshold applicable in Section 6(b) rulemaking applies rather than the heightened Section 6(c) emergency rulemaking prerequisite of "grave danger." OSHA states in its reopening of the docket that, "[a] final standard will be adopted under Section 6(b) of the OSH Act, which requires a finding of significant risk from exposure to COVID–19, rather than the finding of grave danger OSHA made in issuing the Healthcare ETS under Section 6(c) of the OSH Act. Section 6(b) requires that the standard substantially reduce or eliminate significant risk of material impairment of health to the extent feasible. In view of this different risk finding, OSHA is considering whether the scope of the final standard should cover employers regardless of screening procedures for non-employees and/or vaccination status of employees to ensure that all workers are protected to the extent there is a significant risk. OSHA seeks comment on this approach." See 87 FR 16427.

As set forth below, the retail pharmacy industry strongly urges OSHA to preserve this screening exemption, especially if it does not expand the existing, limited retail pharmacist exemption.

# A. OSHA Likely Would Not Be Able to Demonstrate Significant Risk Within the Pharmacy Retail Industry.

There is real question as to whether OSHA could demonstrate even the relaxed "significant risk" threshold for regulation under Section 6(b) of the OSH Act. While the landmark decision by the Supreme Court in *Industrial Union Department, AFL-CIO v. American Petroleum Institute,* 448 U.S. 607 (1980), commonly known as the "Benzene" decision, relates to carcinogenicity risks, it is useful to apply the principles set forth in this decision to the current situation. In the Benzene decision, the Court observed that "the requirement that a 'significant' risk be identified is not a mathematical straitjacket" and that the Secretary's obligation was to "make a *rational judgment* about the *relative significance* of the risks associated with exposure to a particular carcinogen." *See* 448 U.S. at 655, 656-57 (emphasis added). The Court offered the following illustration:

• "If, for example, the odds are *one in a billion* that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are *one in a thousand* that regular inhalation of gasoline vapors that are two percent benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it. Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as 'unsafe."

See id. at 655 (emphasis added).

As of April 16, 2022, the case rate in the United States is 11 per 100,000, or .011%. *See* The New York Times "Coronavirus in the U.S.: Latest Map and Case Count" (April 16, 2022). While clearly this is more than one in a billion, it is an order of magnitude less than one in a

thousand, or .1%. And, 11 per 100,000 is a rate that would never be experienced in a general industry retail pharmacy setting, with or without COVID-19 screening protocols in place. The risk of COVID-19 exposure to retail pharmacists and staff is likely much closer to the far end of the risk scale than the 1 in 1000 rate identified by the Supreme Court. Indeed, unlike hospital or urgent care settings, which draw those with COVID-19 in (i.e., persons suspected or confirmed to have COVID-19 should typically either stay home or go to the hospital or urgent care), if screening protocols are in place, retail pharmacies would actually *turn away* suspected and confirmed cases. Accordingly, based on the Benzene decision, there is good question as to whether OSHA would be able to meet the legal threshold of "significant risk" with respect to retail pharmacies and most definitely could not meet this standard if screening and barring were required.

Even without screening protocols in place, based on the experience pharmacies have had over the last year, it seems clear that pharmacy staff would not spend a substantial portion of their shift actually conducting COVID-testing. And, these contacts would occur only with pharmacy staff suited in appropriate PPE.

Thus, the legal rationale OSHA posited for eliminating the screening exemption and, thereby, imposing the COVID-19 standard on retail pharmacies is questionable. Regardless, the industry is not interested in a legal debate over whether the "significant risk" threshold would be met if OSHA were to apply the permanent healthcare standard to this industry. Rather, it provides these comments to urge OSHA to avoid that debate and, at minimum, preserve the screening exemption it included in the COVID-19 healthcare ETS. Screening has very effectively protected pharmacy staff from any significant risk of COVID-19 transmission in our retail locations.

## B. There is No Scientific Basis for Removal of the Non-Hospital Screening Exemption.

We understand that OSHA may be considering elimination of the screening exemption because screening does not detect asymptomatic or pre-symptomatic individuals who are unaware of any recent close contacts. However, when OSHA issued its Healthcare ETS in June, 2021, it was already well aware of this risk. Nothing has changes since June 2021 in this regard. And while much of OSHA's stated rationale supporting screening relates to employee screening, the same concepts apply to the clientele screening done by pharmacies before provision of vaccinations or immunizations. Regarding screening, OSHA states, "[r]egular health screening for possible indications of COVID-19 is a first step in detecting employees who might be COVID-19-positive so those employees can seek medical care or testing or inform the employer if they have certain symptoms. While pre-symptomatic and asymptomatic infections and the non-specificity of COVID-19 symptoms make it difficult to quantify the accuracy of symptom screening in predicting COVID-19, health screening is a strategy supported by the CDC and the American College of Occupational and Environmental Medicine (ACOEM)." See 86 FR 32376, 32452 (June 21, 2021) (emphasis added).

OSHA goes on to state, "The CDC recommends that employers conduct screening at the worksite, or train employees to be aware of and recognize the signs and symptoms of COVID-19 and to follow CDC recommendations to self-screen for symptoms before coming to work. Screening for employee symptoms, particularly when combined with their recent activities (e.g., the likelihood they have had a recent exposure to COVID-19), can help determine if the employee is suspected to have COVID-19 or should be tested." *See* 86 FR at 32452 (internal citations omitted).

Additional language from the preamble shows that while OSHA recognized the potential shortcomings associated with screening, the agency decided to include an exemption based on screening because it is an effective mitigation strategy nonetheless:

- "Limited contact with potentially infectious persons is a cornerstone of COVID-19 pandemic management. For example, *screening* and triage of everyone entering a healthcare setting *is an essential means of identifying those individuals who have symptoms that could indicate infection with the SARS-CoV-2 virus*. Persons with such symptoms can then be triaged appropriately to minimize exposure risk to employees." *See* 86 FR at 32430 (internal citations omitted) (emphasis added).
- "Symptoms-based screening is a standard component of infection control. This approach was recommended during the 2003 SARS epidemic (caused by SARS-CoV-1, a different strain of SARS) and is routinely recommended for airborne infections such as M. tuberculosis and measles, and as a general practice in infection control programs. Because SARS-CoV-2 can be transmitted by individuals who are infected but do not have symptoms (asymptomatic and presymptomatic transmission), symptom-based screening will not identify all infectious individuals. However, persons with symptoms early in their SARS-CoV-2 infection are among the most infectious. Therefore, symptom-based screening will identify some of the highest-risk individuals for SARSCoV-2 transmission and thereby reduce the risk to workers." See 86 FR at 32430 (internal citations omitted) (emphasis added).
- "In general, the presence of COVID-19 symptoms can alert employees that they may have COVID-19, which will allow them to take appropriate next steps. Thus, by monitoring for COVID-19 symptoms through regular health screening, employees can better address their personal health and avoid potentially infecting other people by seeking medical attention and getting tested for COVID-19 as appropriate; informing their employer if they are suspected or confirmed to have COVID-19, including concerning symptoms; and remaining away from the workplace where appropriate. Therefore, health screening is an effective strategy for preventing the transmission of COVID-19 in the workplace." See 86 FR at 32453 (emphasis added).
- "Paragraph (a)(2)(iii) provides that the ETS does not apply to non-hospital ambulatory care settings where all non-employees are screened prior to entry and people with suspected or confirmed COVID-19 are not permitted to enter those settings. This exception is intended to exclude from the standard certain healthcare providers *that do not treat, and instead exclude from their facilities, people with suspected or*

confirmed COVID-19, either because such treatment is not related to the nature of their practice or because the provider chooses not to engage in such treatment as a matter of policy. The exception will apply so long as the employer meets the exception's conditions: the employer must screen each non-employee prior to entry, make a determination based on that screen whether the non-employee has suspected or confirmed COVID-19, and bar entry to that non-employee if it is determined that the non-employee has suspected or confirmed COVID-19." See 86 FR at 32564 (emphasis added).

- "As defined in paragraph (b), screen means asking questions to determine whether a person is COVID-19 positive or has symptoms of COVID-19. Although it is not a perfect tool, screening is an important aspect of a multi-layered approach to minimizing workplace exposures to COVID-19." See 86 FR at 32571 (emphasis added).
- "The employer needs to be aware that *screening will not identify some employees* who have COVID-19. Some individuals with COVID-19 may be pre-symptomatic (i.e., have not developed symptoms yet) or asymptomatic (i.e., do not develop symptoms over the course of infection) but can still transmit the virus. Therefore, in settings covered by the standard, employers must continue to follow all requirements of the standard, using employee health screening as only one component of a multi-layered approach." See 86 FR at 32589 (emphasis added).

There is no new, additional scientific evidence that was not available to OSHA at the time it promulgated the ETS to suggest that the screening exemption should be eliminated. While certainly the omicron variant was shown to be more transmissible than previous variants, and Ba2 and now Ba2.1 subvariant, all more transmissible than the previous, there does not appear to be any evidence to suggest that it caused more asymptomatic or pre-symptomatic cases. Indeed, in describing the omicron variant, as it was on the rise in December 2021, the CDC stated, "Preliminary information from South Africa indicates that there are no unusual symptoms associated with Omicron variant infection, *and as with other variants, some patients are asymptomatic.*" *See* CDC "Science Brief: Omicron (B.1.1.529) Variant" (updated December 2, 2021) (emphasis added). The use of CDC's "as with other variants" in describing asymptomatic omicron cases goes to suggest that there is nothing particular or unique about omicron in terms of the number of asymptomatic cases. Thus, the effectiveness of screening now is essentially the same as it was back in June 2021, when OSHA promulgated its Healthcare ETS. Therefore, there is no scientific basis for eliminating the screening exemption.

### **Section Two: Contents of the Standard**

While the industry urges OSHA to provide exemptions for coverage from the standard, we provide comment on the content of the standard in the event retail pharmacies are required to comply with its provisions.

### A. OSHA Should Ensure the Standard Provides Flexibility to Comply with Evolving CDC Guidance

OSHA is considering aligning its final rule with some or all of the CDC recommendations that have changed between the close of the original comment period for this rule and the close of this comment period, as well as providing a "safe harbor" enforcement policy for employers who are in compliance with CDC guidance applicable during the period at issue. *See* 87 FR at 16427. We strongly support OSHA in this approach.

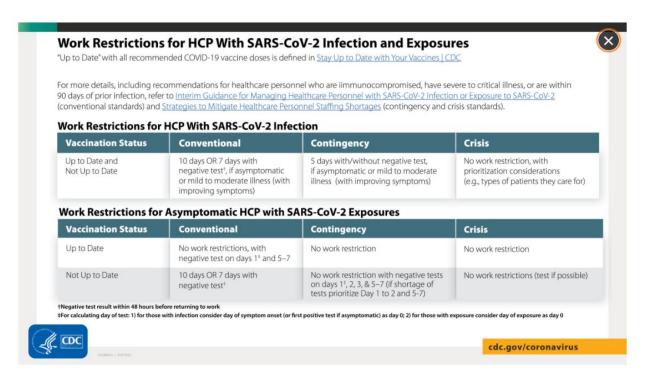
It is imperative that the standard provides flexibility to comply with evolving CDC guidance. CDC has consistently and regularly updated its COVID-19 prevention guidelines based on emerging science and data as it continues to study and gain an understanding of SARS-CoV-2. Over the past two plus years, the CDC has updated workplace-related guidelines multiple times each month, often in ways that directly contradict prior guidance. That is understandable, of course, in the context of any novel virus like SARS-CoV-2. For example, in October 2020, CDC updated its guidance regarding the airborne nature of SARS-CoV-2; prior to that COVID-19 was understood to be principally transmitted by droplets and/or surface contamination. CDC revised its "return-to-work" criteria at least twice over the summer of 2020 – once addressing the recommended number of days of home isolation, and later, within days of Virginia OSHA ("VOSH") issuing its state ETS, eliminating the test-based criteria, which had just been memorialized in the VOSH ETS. Most visibly perhaps, over the course of the pandemic, the CDC rejected the need for face coverings, then recommended their use when distancing could not be maintained, then recommended them for most indoor work, then updated its guidance to consider "double masking," then allowed for fully vaccinated individuals to drop their masks, then recommended that all individuals, including those who are fully vaccinated, wear masks again, and now, recommends masking for the general population based on recently rejiggered county Community Levels.

The lesson from this constantly changing landscape is that any effective standard must provide flexibility to allow employers to revise their programs consistent with updated CDC guidance without running afoul of the standard. While OSHA has considerable expertise in controlling workplace hazards, the coronavirus hazard is not uniquely a workplace hazard – it does not originate in or emanate from the workplace or work practices; it is not a by-product of an operation or task performed at a workplace. Rather, it is a public health hazard coincidentally, inadvertently and unknowingly, carried into the workplace by employees and the public. The pandemic is, first and foremost, a public health concern, rather than a workplace hazard, and as such, the principal policymaker for defeating it should remain the CDC, the preeminent U.S. authority on public health and infectious disease. This is not to say that OSHA does not have jurisdiction to establish a standard requiring mitigation protocols; however, that standard should be fully aligned with the guidelines set by the CDC.

There are a number of inconsistencies between CDC's guidelines and the ETS. Although the CDC notes in its "Strategies for Optimizing the Supply of Facemasks" guidelines that the supply and availability of facemasks have increased significantly over the last several months, and therefore, healthcare facilities should not be using crisis capacity strategies at this time and should promptly resume conventional practices, the CDC at least provides an option for use of

cloth face coverings in combination with face shields when no facemasks are available. *See* CDC "Strategies for Optimizing the Supply of Facemasks" (updated November 23, 2020). The ETS, however, does not provide this option. While we certainly hope that we do not see shortages like those that were experienced over the Spring, Summer, and even Fall of 2020, we do think it is unwise to ignore this possibility, particularly in light of the new, highly transmissible variants that are emerging.

Additionally, there are discrepancies between CDC guidelines and ETS requirements regarding isolation and quarantine rules. The CDC provides the following chart as current guidance for isolation and quarantine for healthcare personnel:



See CDC "Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2" (January 21, 2022).

The ETS, on the other hand, provides:

• If the employer knows an employee meets the criteria listed in paragraph (l)(2)(i) of this section [i.e., the employee is COVID-19 positive (i.e., confirmed positive test for, or has been diagnosed by a licensed healthcare provider with, COVID-19)], then the employer must immediately remove that employee and keep the employee removed until they meet the return to work criteria in paragraph (l)(6) of this section [providing that employers must make decisions regarding an employee's return to work after a COVID-19-related workplace removal in accordance with guidance from a licensed healthcare provider or CDC's "Isolation Guidance" (incorporated by reference, §

1910.509); and CDC's "Return to Work Healthcare Guidance" (incorporated by reference, § 1910.509)]. See 29 C.F.R. Section 1910.502(l)(4)(i).

- If the employer knows an employee meets the criteria listed in paragraphs (l)(2)(ii) through (iv) of this section [i.e., the employee: has been told by a licensed healthcare provider that they are suspected to have COVID-19; or is experiencing recent loss of taste and/or smell with no other explanation; or is experiencing both fever (≥100.4 °F) and new unexplained cough associated with shortness of breath], then the employer must immediately remove that employee and either:
  - Keep the employee removed until they meet the return to work criteria in paragraph (l)(6) of this section [providing that employers must make decisions regarding an employee's return to work after a COVID-19-related workplace removal in accordance with guidance from a licensed healthcare provider or CDC's "Isolation Guidance" (incorporated by reference, § 1910.509); and CDC's "Return to Work Healthcare Guidance" (incorporated by reference, § 1910.509)]; or
  - Keep the employee removed and provide a COVID-19 polymerase chain reaction (PCR) test at no cost to the employee.
    - If the test results are negative, the employee may return to work immediately.
    - If the test results are positive, the employer must comply with paragraph (1)(4)(i) of this section [see first black round bullet above].
    - If the employee refuses to take the test, the employer must continue to keep the employee removed from the workplace consistent with paragraph (l)(4)(ii)(A) of this section [see first while round bullet above], but the employer is not obligated to provide medical removal protection benefits in accordance with paragraph (l)(5)(iii) of this section. Absent undue hardship, employers must make reasonable accommodations for employees who cannot take the test for religious or disability-related medical reasons.

See 29 C.F.R. Section 1910.502(l)(4)(ii).

- If the employer is required to notify the employee of close contact in the workplace to a person who is COVID-19 positive in accordance with paragraph (l)(3)(i)(A) of this section [requiring employers, when notified that a person who has been in the workplace(s) is COVID-19 positive, to, within 24 hours notify each employee who was not wearing a respirator and any other required PPE and has been in close contact with that person in the workplace], then the employer must immediately remove that employee and either:
  - o Keep the employee removed for 14 days; or

- Keep the employee removed and provide a COVID-19 test at least five days after the exposure at no cost to the employee.
  - If the test results are negative, the employee may return to work after seven days following exposure.
  - If the test results are positive, the employer must comply with paragraph (l)(4)(i) of this section [requiring employers to immediately remove the employee and follow applicable return-to-work criteria].
  - If the employee refuses to take the test, the employer must continue to keep the employee removed from the workplace consistent with paragraph (l)(4)(iii)(A)(1) of this section [requiring the employer to keep the employee removed for 14 days], but the employer is not obligated to provide medical removal protection benefits in accordance with paragraph (l)(5)(iii) of this section. Absent undue hardship, employers must make reasonable accommodations for employees who cannot take the test for religious or disability-related medical reasons, consistent with applicable non-discrimination laws.

See 29 C.F.R. Section 1910.502(l)(4)(iii).

Although OSHA incorporates by reference CDC guidelines in its Healthcare ETS return-to-work provisions, those guidelines are outdated. For example, CDC's "Isolation Guidance," to which OSHA refers, is from February 28, 2021. The CDC's "Return to Work Healthcare Guidance" that is incorporated by reference is from April 27, 2021. These have both changed significantly since December 2021. OSHA's 14-day quarantine requirement is outdated as well.

Presumably, OSHA does not dispute the expertise of CDC in making specific recommendations applicable specifically to the healthcare industry; yet OSHA seems to either second-guess or ignore those recommendations and set the agency's own standard. Consistent guidance between federal agencies is critical and it is imperative that OSHA's requirements align fully with applicable CDC guidance. Because OSHA's ETS is a static regulation whereas CDC's guidance is ever-changing based on the evolving study of this virus, a mechanism must be built into the standard to address this situation.

To that end, we endorse the adoption of an approach similar to that included in Virginia's COVID-19 standard (rescinded on March 23, 2022) promulgated by the Virginia Occupational Safety and Health Administration ("VOSH"). As OSHA likely recalls, it was only days after VOSH issued its ETS that the CDC upended its "return-to-work" guidance, leaving a major element of VOSH's ETS out of step with the current scientific consensus only days after the ETS was issued. Other elements of the VOSH rule similarly fell behind current CDC guidance over the next few months. This misalignment was not problematic, however, because VOSH had the foresight to build into the standard flexibility necessary to keep up with the evolving science and data related to the virus. Specifically, VOSH incorporated a provision that essentially allowed employers to be deemed in compliance with the ETS if they complied with updated CDC guidelines, even where they conflict with a specific term in the ETS. See 16VAC25-220-10(E) (rescinded). We urge OSHA to add a similar provision to the federal standard. This will

address the existing inconsistencies but, as or more important, will allow the regulated community to continue to be guided by the CDC without risk of non-compliance with OSHA's standard.

Cal/OSHA and the California Occupational Safety and Health Standards Board did not follow the same approach as VOSH, and experienced the same types of issues, but without an efficient mechanism to address them because no such flexibility provision was included in California's ETS. For example, only a few days after Cal/OSHA's ETS went into effect, the CDC relaxed its quarantine guidelines, prompting the California Department of Public Health ("CDPH") to update its COVID-19 Quarantine Guidance, and Governor Newsom to issue an Executive Order ("EO") regarding the same. *See* CDC, "CDC Options to Reduce Quarantine for Contacts of Persons with SARS-CoV-2 Infection Using Symptom Monitoring and Diagnostic Testing" (updated December 2, 2020) (archived); *see also* CDPH, "COVID-19 Quarantine Guidance" (December 14, 2020); and California EO N-84-20 (December 14, 2020). Despite the EO suspending some of the then-outdated and conflicting Cal/OSHA ETS requirements, this caused significant confusion and uncertainty among the regulated community because the ETS was no longer aligned with the revised position of the executive branch.

To keep up with evolving science and avoid confusion, we urge OSHA to include regulatory text in the standard itself that allows employers to follow current CDC guidance, such as:

To the extent an employer complies with an applicable recommendation contained in CDC guidelines, whether written in mandatory or non-mandatory terms, to mitigate COVID-19 related hazards addressed by this standard, even if the CDC guidelines conflict with the terms of this standard, the employer's actions shall be considered in compliance with the related terms of this standard.

Failure to bake into the standard this flexibility will risk OSHA's requirements continually lagging, making it nearly impossible for any covered employers to consistently follow.

### B. The Standard Should be More Performance-Oriented as OSHA is Considering

We understand that OSHA is considering restating various provisions as broader requirements without the level of detail included in the Healthcare ETS. *See* 87 FR at 16427. We strongly support OSHA in this regard, including with respect to the provisions OSHA specifically identifies -- criteria for medical removal and return to work, cleaning, ventilation, barriers, aerosol-generating procedures. *See id.* 

There is no "one-size-fits-all" approach to tackling the hazards of COVID-19. While employers have similar goals, their approaches, by necessity, are very different. Revising the standard to make it more performance oriented makes sense at least in part because of the diverse set of occupational settings OSHA intends to regulate, but also because of the complexity associated with assessing and mitigating COVID-19 hazards. There are myriad factors relevant to determining whether COVID-19 presents a significant risk. For example, community level of transmission, vaccination status of the workforce, and whether there are any workers at higher risk of severe infection, to name a few. Based on the factors that OSHA has determined are

impactful and relevant to this hazard, even within the same company – and at times even within the same *facility* – there can be still substantial variability with respect to the severity of the hazard.

Additionally, there are countless effective approaches to address the COVID-19 hazard, as demonstrated by the programmatic style of the ETS. While there are some common threads in the approaches employers utilize to mitigate the COVID-19 hazard, there are many differences as well. For example, while physical distancing may be feasible in large hospital settings, as described above, it tends to be infeasible in smaller retail pharmacy settings. There just is no way for OSHA to effectively regulate COVID-19 hazards through a prescriptive standard. Accordingly, coalition members urge OSHA to revise the ETS to make it more performance oriented and flexible. As a model for this type of standard, OSHA should look to the performance-oriented Process Safety Management ("PSM") Standard. The PSM standard was met with substantial support from the regulated community in large part because it allows employers to consider and address the specific needs of their particularized workplaces in establishing workplace requirements. In the preamble to the final rule, OSHA provides:

Participants in the rulemaking also supported OSHA's development of a performanceoriented standard. The Chemical Manufacturers Association remarked: [']Initially CMA would like to commend OSHA on its efforts to craft a comprehensive performancebased standard addressing process safety management of highly hazardous chemicals. As CMA has commented in past rulemakings, performance language capitalizes on industry's ingenuity and capability to effectively reduce hazards as they may be *uniquely applied to a particular safety concern.*['] Ashland Petroleum Company stated: ['] Ashland \* \* \* is generally supportive of the efforts of the Secretary and of the Occupational Safety and Health Administration with respect to this proposed regulation. While our internal commentors had divided between a desire for specificity and the obvious value of the non-detailed performance approach, ultimately we believe the "performance standard" approach is the best way to regulate a wide variety of situations for which a common end is desired.[1] The American Society of Safety Engineers noted: [']The Society commends *OSHA's use of a performance standard* rather than a specification rule, believing this is the better means to help ensure each affected facility address its individual situation.[']

*See* 56 FR 6356, 6360 (February 24, 1991) (exhibit references omitted) (emphasis added). Likewise, for similar reasons, a COVID-19 standard would be most effective if it allows for a flexible, performance-oriented approach to achieve overarching objectives.

# C. OSHA Should Tailor Controls to Address Interactions with People with Suspected or Confirmed COVID-19.

OSHA also is considering relaxation or elimination of implementation of specific infection control measures in areas where employees are not reasonably expected to encounter people with suspected or confirmed COVID-19. *See* 87 FR at 16427. OSHA mentions that "[t]his could include eliminating certain requirements that were included in the Healthcare ETS and that applied to all areas of covered healthcare settings. For example, OSHA could consider imposing

cleaning requirements or medical removal provisions only with respect to staff exposed to COVID-19 patients or eliminating facemask requirements for staff not exposed to COVID-19 patients." *See id.* The coalition strongly supports OSHA in this approach.

# D. OSHA Should Include a Set Requirement for Paid Time Up to Four Hours for Employees to Receive a Vaccine and Paid Sick Leave to Recover From Side Effects

OSHA is considering an adjustment to the paid leave requirement that would establish a set amount of paid time of up to 4 hours, including travel time, for employees to receive a vaccine and paid sick leave to recover from side effects and seeks comment on the approach." *See* 87 FR at 16428. Our coalition of retail pharmacies supports such an approach and agrees that it would be beneficial to expressly establish a requirement that employers provide a combined four hours to each employee for vaccination and recovery from any side effects.

# E. OSHA Should Limit the Provisions That Provide Support for Vaccination to Employees Not Covered by the Centers for Medicare & Medicaid Services Vaccination Rule.

The coalition recognizes that OSHA is "considering whether to limit the provisions that provide support for vaccination to employees not covered by the Centers for Medicare & Medicaid Services ("CMS") vaccination rule[.]" See 87 FR at 16428. OSHA explains that "[t]he CMS vaccination rule requires healthcare staff in facilities regulated by CMS to be vaccinated. The majority of healthcare employees covered by this final rule work in facilities covered by the CMS vaccination rule and are subject to the CMS requirements." See id. Although retail pharmacy employees are not covered by the CMS vaccination rule, the coalition supports limiting the provisions that provide support for vaccination to employees not covered by the CMS vaccination rule, as it is inherently not necessary to support vaccination where vaccination is required.

Despite not being covered by the CMS vaccination rule, the coalition would like to note that retail pharmacies have been working for months to facilitate vaccinations for our workforces. Indeed, some retail pharmacies implemented their own vaccine mandates, where others provided substantial financial incentives to encourage vaccination. They have offered vaccines onsite, provided paid time off to get vaccinated and recover from side effects, provided comprehensive training and education on the benefits of vaccination, and so on. As a result, in addition to playing a critical role in the administration of the vaccine, retail pharmacies have successfully achieved high rates of vaccination among their pharmacy staff.

# F. The Permanent Standard Should Allow for Relaxed Requirements Where a High Percentage of Staff is Vaccinated.

OSHA is considering relaxation of masking, barriers, and physical distancing, but only for vaccinated workers. *See* 87 FR at 16428. We agree that relaxed requirements of these requirements makes sense, but we recommend that the relaxation be triggered based on a percentage of the workforce being fully vaccinated rather than distinguishing between those employees who are and are not vaccinated. Masking in particular has become a hotbed

political issue and tension likely will arise for any employer who provides "a benefit" to those employees who are vaccinated that is not available to unvaccinated employees. To single out individual staff members and require more of unvaccinated employees has proven to be problematic from an employee relations perspective, and, not the model OSHA followed in its Bloodborne Pathogen Standard (BBP), where it did not mandate any additional infection control procedures or administrative controls for those employees who decline the hepatitis-B vaccine.

However, an across-the-board relaxation of these requirements once a workplace achieves a high percentage of vaccinated employees overall does not present the same concerns, yet still establishes an incentive for employees to become vaccinated.

# G. The Permanent Standard Should Include Express Language That KN95s With Ear Loops Are Not Respirators Under OSHA's Respiratory Protection Standard.

We understand that OSHA, correctly in our view, does not consider KN95s with ear loops to be respirators under OSHA's Respiratory Protection Standard, 29 C.F.R. Section 1910.134. Per the Healthcare ETS, "Respirator means a type of personal protective equipment (PPE) that is certified by NIOSH under 42 CFR part 84 or is authorized under an EUA by the FDA. Respirators protect against airborne hazards by removing specific air contaminants from the ambient (surrounding) air or by supplying breathable air from a safe source. Common types of respirators include filtering facepiece respirators, elastomeric respirators, and PAPRs. Face coverings, facemasks, and face shields are not respirators." See 29 C.F.R. 1910.502(b) (bold emphasis added). For some time, KN95s were authorized under an EUA by the FDA, but that authorization was revoked on July 6, 2021 (the same day that covered employers were required to comply with most of the provisions of the Healthcare ETS, including the personal protective equipment ("PPE") provisions). See FDA, "Revoked EUAs for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators" (content current as of June 30, 2021).

Significant confusion continues over this issue. OSHA should use this rulemaking to clarify its position by setting forth a note in the definition of "respirator" to state that KN95s with ear loops are not considered respirators under 29 C.F.R. 1910.134. This will clear much confusion among the regulated community, as well as among employees, who commonly mistake KN95s for respirators (and thus, request fit testing, medical evaluations, etc.). Many of our coalition members would like to continue providing KN95s with ear loops to our staff, but would like assurance that by doings so we are not triggering additional regulatory compliance obligations.

### H. The Permanent Standard Should Include a Sunset Provision

Any permanent COVID-19 standard should include a sunset provision. OSHA is seeking comment on whether the permanent standard should apply "not only to COVID-19, but also to subsequent related strains of the virus that are transmitted through aerosols and pose similar risks and health effects." *See* 87 FR 16428. We urge OSHA to not take such an approach. This standard has been designed to address the unique characteristics of transmission of the SARS-CoV-2 virus and required mitigation strategies and prevention techniques tailored to prevent transmission of this particular coronavirus. The agency is also engaged in a separate

rulemaking to promulgate a broad infectious disease standard applicable to the healthcare industry. The COVID-19 standard should include a sunset provision that expires the standard upon either the promulgation of an infectious disease standard, or based on some designated official status, such as the President declaring an end to the National Emergency Status or the World Health Organization (WHO) removing the global pandemic designation from the public health crisis description, whichever comes first. The standard should serve its purpose, and then expire.

This is not to say that the lessons learned from the mitigation strategies employed during this pandemic should not inform the agency in another, broader rulemaking to develop an infectious disease standard. However, the ETS should not automatically transform into that.

### **CONCLUSION**

The coalition respectfully requests that OSHA give meaningful consideration to these comments and recommendations in considering the development of any permanent COVID-19 Healthcare standard.

Sincerely,

Eric J. Conn

Chair, OSHA Practice Group Conn Maciel Carey LLP